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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,885	03/01/2004	Richard Kaplan	204589-0010	2598

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DRINKER BIDDLE & REATH LLP  
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CHICAGO, IL 60606

EXAMINER
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COLQUITT, AARON BRUCE

ART UNIT	PAPER NUMBER
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3735

MAIL DATE	DELIVERY MODE
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07/19/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/790,885		KAPLAN ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Aaron B. Colquitt		3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06/21/2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 38-70 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 38-43, 46-70 is/are rejected.
- 7) ☐ Claim(s) 44 and 45 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/12/2004, 7/25/2005</u> .                                    | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Claim Objections***

Claims 44, 45, 51, 53, 59 and 63 are objected to because of the following informalities:

- a. At claim 44, line 7, "the second" should read --a second--.
- b. At claim 45, line 4, "contiguous" should be deleted in order to maintain consistent terminology for the claim limitation.
- c. At claim 51, line 1, --for-- should be inserted following "means".
- d. At claim 53, line 1, --for-- should be inserted following "means".
- e. At claim 59, line 1, --for-- should be inserted following "means".
- f. At claim 63, line 1, --for-- should be inserted following "means".

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 39, 40, 44, 45 and 50 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Regarding claims 38 and 50, the original disclosure does not support use of the system and apparatus of the instant application to implement "relaxation therapy" and

"cognitive behavioral therapy". Regarding claim 44, the original disclosure of the instant application provides support for a maintenance flag but fails to support a "maintenance mode".

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 38-46, 48, 49, 56-58, 60, 63 and 67-70 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 38 recites the limitation "the steps of the behavioral therapy" in line 7. There is insufficient antecedent basis for this limitation in the claim. There are no steps recited in the claim prior to this recitation.

Claim 46 recites the limitation "the behavioral therapy parameters" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. There are no parameters recited in the claims prior to this recitation.

Claim 48 recites the limitation "the rules of the stimulus control therapy" in lines 4-6. There is insufficient antecedent basis for this limitation in the claim. There are no rules recited in the claims prior to this recitation.

Claim 49 recites the limitations "the program parameters" in line 3 and "the rules of the sleep restriction therapy" in line 5. There is insufficient antecedent basis for these limitations in the claim. There are no program parameters or rules recited in the claims prior to these recitations.

Claims 56 and 57 recite the limitation "means are provided for turning off any alert" in line 2. There is insufficient antecedent basis for this limitation in the claim. There are no alerts recited in claims 47 or 55-57 prior to this recitation.

*Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3843, 46-54, and 58-69 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5928133 to Halyak (of record).

In Reference To Claim 38

An automated system for facilitating the implementation of behavioral therapy that uses information indicative of a subject's wake/sleep state to improve the subject's sleep or sleep hygiene, including subjects with insomnia or other sleep complaints, comprising:  
passive wake/sleep determination means for producing information indicative of the subject's wake/sleep state; (column 2, lines 49-58) and  
means for implementing the steps of the behavioral therapy utilizing the wake/sleep information (column 4, lines 11-24).

In Reference To Claims 39-41, 43, 46

Halyak teaches of a combination of therapies in column 2, line 59 to column 3, line 3 wherein information of the stimulus (diet, exercise, etc) and restriction/relaxation (alarm) are used. This

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system also uses EEG's, heart rate, movement sensors, galvanic skin response, and other parameters for sleep research (column 3, lines 58-67), where the user can calibrate the values that are most efficacious for the user (column 5, lines 10-15).

**In Reference to Claim 42**

Claim 42 fails to further limit the structure of the claimed apparatus and merely defines the intended use of the present invention. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In this case, the apparatus of Halyak meets all of the structural limitations of the claim and is fully capable of performing the claimed intended use.

**In Reference To Claim 47** An apparatus for facilitating the implementation of behavioral therapy for a subject seeking to improve the subject's sleep or sleep hygiene, including subjects with insomnia or other sleep complaints, comprising:

means for processing information taken from the group consisting of: EEG, EKG, EMG, EOG, actigraphy, body movement, galvanic skin response, respiratory changes, eye movements and combinations of two or more thereof to determine the subject's wake/sleep state; and means for implementing the behavioral therapy utilizing the wake/sleep state information (column 3, line 58 to column 4, line 55).

**In Reference To Claims 48-54, 58-69**

Halyak teaches that the use of an apparatus that can record varying resistance values can determine when a user should be woken up and that time can be calibrated (column 4, lines 38-

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42 and column 3, lines 27-33) to the user's needs (column 5, lines 1-15) over a length of time (column 4, lines 10-13) that can be viewed on a monitor or printed for a record of the sleep session (column 4, lines 11-24). The apparatus is capable of being worn by the user (column 4, lines 5-10) and can wake the user with an alarm (column 5, lines 20-23) that alerts the user either after the sleep period has been completed (column 5, lines 16-34) or as a failsafe.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 55-57 and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Halyak in view of US 6392962 to Wyatt (of record).

**In Reference To Claims 55-57, and 70**

Halyak meets the limitations of the dependent claim but fails to mention whether the subject is in bed or not.

Wyatt, however, teaches of a sleep disorder treatment involving a timer that can be attached to an insomniac's bed, etc (column 6, lines 5-10). The touch pad (24) engages the time to be measured when connected and stops when the pads are disconnected (column 6, lines 43-52). The timer located on the bed can either record time when the pads are connected or disconnected (column 6, line 53 to column 7, line 9) and thus can acquire wake/wake information and can determine if the subject is in bed and display it on either a monitor or printer.

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teachings of Wyatt with that of Halyak to develop a sleep therapy system and apparatus that is able to determine whether or not the user is in bed along with their wake/sleep state information.

*Allowable Subject Matter*

Claims 44 and 45 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:

No prior art of record teaches or fairly suggests an apparatus including means for implementing a stimulus control therapy having the rules recited in claim 44.

*Conclusion*

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 599846 to Pardey et al., 5846206 to Bader, 2006/0246129 to Linardakis et al., 2004/0087878 to Krausman et al., are considered pertinent to the applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron B. Colquitt whose telephone number is (571) 270-1991.

The examiner can normally be reached on Mon-Friday 9-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AC



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